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**DATE:** September 12, 2002

**FROM:** Director  
Survey and Certification Group  
Centers for Medicare & Medicaid Services

**SUBJECT:** Centers for Disease Control and Prevention (CDC) Revised Recommendations for Single-Use Intravenous Medication Vials in End-Stage Renal Disease (ESRD) Facilities

**TO:** Associate Regional Administrator, DMSO  
State Survey Agency Directors

The purpose of this program memorandum is to provide information and guidance to regional offices, state survey agency personnel, and ESRD facilities regarding revised guidance issued by the Centers for Disease Control and Prevention (CDC) on infection control practices to be followed in End-Stage Renal Disease (ESRD) facilities.

The Survey Procedures and Interpretive Guidelines for End Stage Renal Disease Facilities state that facilities should institute the current recommendations of the CDC relative to infection control and prevention. The current (April 27, 2001) guidelines from the CDC state "intravenous medication vials labeled for single use, including erythropoietin, should not be punctured more than once." Accordingly, surveyors have been citing the practice of multiple-use of single-use vials since the CDC issued that recommendation.

However, we have been aware that for several months the CDC has been reconsidering its position on the repeated use of single-use vials. Please find in the attachment, CDC's revised recommendations. As a result of this issuance, CMS is altering the guidance to states and regions regarding infection control and multiple-use of single use vials.

Effective immediately, ESRD facilities will be expected to follow the revised CDC recommendations for injectable medications administered by ESRD facilities. The CDC has stated that failure to comply with the following recommendations poses a significant health and safety risk to patients. Therefore, we expect that either facilities will continue the practice of single use of single-use vials or facilities will follow the following recommendations:

1. All doses must be drawn-up by a licensed professional whose scope of practice includes administration of parenteral medications and knowledge of aseptic technique.
2. All doses from a given vial should be drawn-up and administered within a 4-hour period.
3. Only one vial of a given concentration of the medication should be opened and used by the administering professional at any given time. A second vial of the same medication must not be opened until the previous vial is discarded.
4. Any opened vials or filled syringes (with epoetin alpha, iron, or vitamin D) must be discarded if not used within 4 hours of first puncture of the vial. Vials must be labeled to document the time of first entry and maintained at a temperature of 2-8 degrees Celsius (or 36-46 degrees Fahrenheit) during non-use.
5. Residual amounts of these medications (either in the vial or syringes) must never be pooled with medication from another vial or syringe. If a patient requires more medication than is in a single, drawn syringe, then medication from a separate vial should be drawn into a separate syringe for administration.
6. Each facility must have in place a process monitoring (quality assurance) program which ensures compliance with these policies and procedures. These policies must include: a) recording data on infections in treated dialysis patients; and b) unannounced practice audits involving quality assurance staff observing performance of re-use techniques.

Regional offices and state survey agencies are now asked to monitor ESRD facilities based upon these revised CDC guidelines. The CDC emphasized, when issuing the new guidelines, that these procedures must be followed strictly to ensure patient health and safety.

This revised information will be added to the SOM, Appendix H, the next time it is revised. Please share additional copies of this memorandum as necessary. If you have further questions, please contact Judith Kari of my staff at [jkari@cms.hhs.gov](mailto:jkari@cms.hhs.gov) or (410) 786-6829.

/s/

Steven A. Pelovitz

Attachment